IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	**Redacted - Public Version** C.A. No. 21-1317-GBW-SRF [redacted]

DEFENDANTS' BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS OF MR. JOHN JAROSZ AND DR. CRAWFORD DOWNS

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[1] Because each of the eight motions relies on its own facts, and for the convenience of the Court, Alcon recites the facts for each motion in conjunction with each argument.

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*All emphasis added, and citations and marks omitted, unless otherwise indicated.

I. NATURE AND STAGE OF THE PROCEEDINGS

Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc. (collectively "Defendants" or "Alcon") respectfully request that the Court exclude the below unreliable opinions of Plaintiff Sight Sciences, Inc.'s ("Sight") experts.

II. SUMMARY OF THE ARGUMENT

Expert witnesses must be qualified, and their testimony must help the trier of fact, be based on sufficient facts or data, and be the product of reliable principles and methods that are reliably applied to the facts of the case. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 589-91 (1993). Plaintiff's experts opine on numerous issues that require the Court to exercise its gatekeeping function. ***First***, Mr. Jarosz relies on the double-hearsay results of a questionnaire designed solely by trial counsel that suffers from myriad methodological flaws rendering it unreliable. ***Second***, Mr. Jarosz's reliance on unverified and untested attorney-fed information regarding incremental costs renders his lost profits opinion unreliable. ***Third***, Mr. Jarosz relies on data he admits is off by an order of magnitude, rendering his incremental benefits reasonable royalty calculation unreliable. ***Fourth***, Mr. Jarosz's and Dr. Down's opinions regarding apportionment are unreliable because they fail to separate the patented and unpatented features of the accused Hydrus. ***Fifth***, Mr. Jarosz's and Dr. Downs's opinions rely on a settlement agreement that is neither economically nor technically comparable. ***Sixth***, Dr. Downs admits he is not an expert on the FDA regulatory process or PTO procedure, but nonetheless renders opinions that require such expertise. ***Seventh***, Dr. Downs applies several new claim constructions, some of which directly contradict the Court's claim construction Order. ***Eighth***, Dr. Downs's alleged "strain analysis" is unreliable because it is based on unsupported assumptions. These opinions of Mr. Jarosz and Dr. Downs should be excluded.

III. MR. JAROSZ'S OPINIONS RELYING ON AN UNRELIABLE QUESTIONNAIRE OF SALES REPRESENTATIVES SHOULD BE EXCLUDED

Based only on the double-hearsay results of an April 2023 questionnaire of Sight sales representatives designed solely by Orion Armon ("Trial Counsel's Questionnaire"), Mr. Jarosz opines that Hydrus displaced many sales of OMNI. *See* Ex. 10, Jarosz Op. Rep. ¶¶64,162, 226; Ex. 20, Papini Tr. at 140:19–141:8; 143:17–23. Trial Counsel's Questionnaire contained two leading questions asking respondents to list "OMNI accounts that have been harmed by competition with Ivantis/Alcon" and "prospective accounts that refuse to try OMNI because Ivantis/Alcon." Ex. 50, IVANTIS_SS_00470628. The questions included exemplar answers detailing presumed harm to OMNI accounts by Ivantis/Alcon. *See id.* The emails distributing the questionnaire were sent by Sight supervisors to their reports, explicitly stating that Trial Counsel's Questionnaire was being conducted for this litigation and asking for "help." *See* Ex. 57, SGHT0170173. [redacted] *See* Ex. 56, SGHT0166268; Ex. 20 at 167:23–169:22. [redacted] *See* Ex. 60 at E38, F27. Despite the blatant methodological flaws, Mr. Jarosz failed to analyze the reliability of Trial Counsel's Questionnaire or the double-hearsay responses, and instead blindly relied on the hearsay responses as evidence of lost accounts and harm to Sight. The Court should exclude Mr. Jarosz's opinions regarding Trial Counsel's Questionnaire (Ex. 10 ¶¶64, 88, 162, 226–233).

Sight has no survey expert to vouch for the reliability of the double-hearsay results from Trial Counsel's Questionnaire. Because surveys are often used to demonstrate the truth of respondents' answers, courts require that they be "conducted in accordance with generally accepted survey principles" in order to admit them. *Pittsburgh Press Club v. U.S.*, 579 F.2d 751,

757–58 (3d Cir. 1978). Here, neither Mr. Jarosz nor any other Sight witness made any attempt to demonstrate that Trial Counsel's Questionnaire and results were "the product of reliable principles and methods" and "based on sufficient facts or data." Fed. R. Evid. 702. Nor could they. Trial Counsel's Questionnaire was designed, and all the double-hearsay responses were documented, by Orion Armon, Sight's ***trial counsel*** (who is not a survey expert). *See* Ex. 20, Papini Tr. at 140:19–141:8 ("Orion had put together a survey and sent the link to me"; "Q. And who drafted the questions? A. I believe it was counsel."); *id*. at 144:10-14; *see also* Ex. 12, Gal Rep. ¶24 (citing https://www.cooley.com/people/orion-armon). That alone justifies exclusion. Moreover, Sight has prejudiced Alcon by effectively barring cross-examination into the questionnaire's design, unless Alcon calls Sight's trial counsel to the stand. MODEL CODE OF PRO. CONDUCT R. 3.7 (AM. BAR ASS'N). This further justifies exclusion of Mr. Jarosz's opinions and testimony about Trial Counsel's Questionnaire. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l*, 711 F.3d 1348, 1373 (Fed. Cir. 2013) ("Rule 703 cannot be used as a backdoor to get the evidence before the jury" where, as here, "the underlying source is so unreliable as to render it more prejudicial than probative.").[2]

The questionnaire's numerous methodological flaws are apparent and catalogued by Dr. Gal, Defendants' unrebutted survey expert. For example, the questionnaire targets the wrong population by questioning sales representatives instead of physicians, making it of little probative value. *See* Ex. 12, Gal Rep. ¶¶27–28; *Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank of Evans City*, 383 F.3d 110, 119 (3d. Cir. 2004) ("A survey of the wrong universe will be of little probative value in litigation."). Additionally, the design created biased, unreliable results by

[2] Defendants will also provide evidentiary objections to the admissibility of the questionnaire, results, and related exhibits in connection with the pretrial order.

notifying both the respondents and the administrators that the questionnaire was specifically designed for use in this litigation. *See* Ex. 12, Gal Rep. ¶¶25–26, 34–35; *Pittsburgh Press Club*, 579 F.2d at 759 (excluding survey where respondents were interested in lawsuit, and aware of survey's purpose and which answers would be beneficial). Trial counsel's questions and exemplar answers also were leading, infusing additional bias into the responses. *See* Ex. 12, Gal Rep. ¶¶42–45; *Brokerage Concepts, Inc. v. U.S. Healthcare Inc.*, 140 F.3d 494, 516 n. 14 (3d. Cir. 1998) (survey erroneously admitted where questions "improperly slant the response"). Further, flawed instructions were provided as to how to answer. *See* Ex. 12, Gal Rep. ¶¶29–33; *U.S. v. Dentsply Int'l., Inc.*, 277 F. Supp. 387, 436 (D. Del. Aug. 8, 2003) ("[F]lawed instructions impact the reliability of the survey data...."). There was also no evaluation of non-response or coverage error. *See* Ex. 12 ¶¶36–39; *Barry v. DePuy Synthes Prods., Inc.*, 2023 WL 4851411, *7 (E.D. Pa. July 28, 2023) (excluding survey where no evaluation of non-response bias).

Notably, neither Sight nor Mr. Jarosz acknowledged, much less addressed, Dr. Gal's criticisms. *See* Ex. 22, Jarosz Tr. at 289:7–12; 286:9–14; *see generally* Ex. 11, Jarosz Rpl. Rep. It is therefore unrebutted that Trial Counsel's Questionnaire and its double-hearsay results suffer from such flaws and the Court should exercise its gatekeeping role to exclude them Mr. Jarosz's reliance on them. *See* Fed. R. Evid. 703; *Citizens Fin. Group*, 383 F. 3d at 120–121 (affirming exclusion of expert that relied on survey with "fundamentally flawed [methodology] and because the danger of undue prejudice far outweighed the limited probative value of the survey, especially for a jury."). Because Trial Counsel's Questionnaire was prepared solely by trial counsel and suffers from numerous methodological flaws that lead to unreliable results, cross-examination is not the appropriate means of challenging Mr. Jarosz's opinions based on them. *See Daubert*, 509 U.S. at 596 ("vigorous cross-examination" is "the appropriate safeguard[]

where the basis of scientific testimony ***meets the standards of Rule 702***."); *Citizens Fin. Grp., Inc.*, 383 F.3d at 121 (affirming exclusion under *Daubert* because surveys suffering from "fatal flaws," not "mere technical flaws," go to admissibility, not weight). Defendants respectfully submit that the Court should exclude Mr. Jarosz's opinions regarding the unreliable questionnaire and its double-hearsay results (Ex. 10, Jarosz Op. Rep. ¶¶64, 88, 162, 226–233).

IV. MR. JAROSZ'S LOST PROFITS OPINION RESTS ON UNVERIFIED, ATTORNEY-FED ASSUMPTIONS REGARDING INCREMENTAL COSTS AND HIS UNRELIABLE OPINION SHOULD BE EXCLUDED

Mr. Jarosz opines that Sight is entitled to lost profits for OMNI, which he calculated by taking (i) Sight's alleged lost revenue and (ii) subtracting Sight's incremental costs associated with selling additional units. *See* Ex. 10, Jarosz Op. Rep. ¶97, Tab 15. This motion focuses on the unreliability of the second input: Sight's incremental costs. Instead of calculating Sight's incremental costs himself by evaluating Sight's actual financials, Mr. Jarosz abdicated that role to Sight's Vice President of Sales, Mark Papini. The entirety of Mr. Jarosz's incremental costs "analysis" in his opening report boils down to this single sentence: "[redacted] Ex. 10, Jarosz Op. Rep. ¶97.

Despite admitting that Mr. Papini is "marketing and sales oriented," not finance-oriented, Mr. Jarosz relied on Mr. Papini for his incremental costs input without any "support for the accuracy of the statements and figures" in Mr. Papini's declaration. Ex. 22, Jarosz Tr. at 104:19–22; *MOSAID Techs. Inc. v. LSI Corp.*, 2014 WL 807877 at *3 (D. Del. Feb. 18, 2014) (excluding lost profits opinion). Mr. Jarosz took such statements at face value without even speaking with Mr. Papini to find out the latter's understanding of "incremental cost." Ex. 22, Jarosz Tr. at 105:1-22. That failure alone justifies exclusion. *See Bruno v. Bozzuto's, Inc.*, 311 F.R.D. 124, 137 (M.D. Pa. 2015) ("[E]xperts who use data in their reports without independently verifying

the accuracy or reliability of those figures fail to satisfy this Circuit's reliability requirement."); *Legendary Art, LLC v. Godard*, 2012 WL 3550040 at *3 (E.D. Pa. Aug. 17, 2012) (damages analysis unreliable absent "evidence [the damages expert] did anything to verify" underlying data); *Chemipal Ltd. v. Slim-Fast Nutritional Foods Int'l, Inc.*, 350 F. Supp. 2d 582, 589 (D. Del. 2004) (excluding damages opinion when expert "did not conduct any independent analysis . . . and does not know what the data represents, how it was compiled, or how it as [*sic*] evaluated or chosen[.]"); *accord Jacked Up, L.L.C. v. Sara Lee Corp.*, 807 Fed. App'x. 344, 349 (5th Cir. 2020) (failure to make "independent determination" of data's accuracy fatal).

Had he spoken to Mr. Papini, Mr. Jarosz would have learned that Mr. Papini ***does not even know what an incremental cost is***. Ex. 20, Papini Tr. at 254:2–3, 254:13–17. He would have further learned that ***trial counsel*** selected and fed Mr. Papini the information upon which Mr. Jarosz subsequently relied. *Id*. at 255:9–16. And he would have also learned that Mr. Papini ***never confirmed*** with anyone at Sight that—as trial counsel told [redacted] *Id*. at 254:13–17; *see ZF Meritor, LLC v. Eaton Corp*, 696 F.3d 254, 292 (3d. Cir. 2012) (excluding lost profits opinion because expert "was unaware of the qualifications of the individuals who prepared the [data]"). Expert opinions that rely on attorney-fed financial inputs without independently verifying them are inadmissible under Rule 702. *See* Fed. R. Evid. 702; *In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 797 & n.9 (M.D. Pa. 1996) (excluding expert testimony that relied on "assumed and unverified source term supplied by attorneys" that expert "whole-heartily [*sic*] accept[ed]" without "attempting to verify the terms").

After receiving Defendants' rebuttal reports criticizing his blind reliance on Mr. Papini, Mr. Jarosz in his reply report attempted to backfill his analysis by talking to Jim Rodberg,

Sight's VP of Finance. Ex. 11, Jarosz Rpl. Rep. n. 149. Mr. Rodberg, however, repeated the same error as Mr. Papini and merely parroted the same attorney-fed information. *Id*. As an indication of his unreliability as a witness, Mr. Rodberg asserted that "Mr. Papini is generally knowledgeable about Sight's cost structure and how cost can change with respect to its sales," *id*., contrary to Mr. Papini's own admissions that he is "not a finance guy" and he does not know what an incremental cost is. Ex. 20, Papini Tr. At 388:19–22.

At his deposition, Mr. Jarosz attempted to further backfill what was absent from his opening report, insisting he had independently analyzed incremental costs at the time of his opening report but failed to put it in writing. Ex. 22, Jarosz Tr. At 100:20–101:4 ("Q: Nowhere in your opening report do you go through an analysis in writing to determine what is or is not an incremental cost, correct? A: Not in writing. I discussed that more in my third report what I had done. . . ."); *id.* at 102:2–7 ("Q: But you didn't include an explanation of that analysis in your opening report, correct? A: I did not."). Even if Mr. Jarosz had performed an incremental cost analysis of his own (and that is doubtful), his failure to disclose it in his opening report violates Fed. R. Civ. P. 26(a)(2)(B)(i) (expert report must include "complete statement of all opinions… and the basis and reasons for them"), and any reply is therefore improper and should be stricken. *See Zimmer*, 365 F. Supp. 3d at 502 (striking new theory in reply); Fed R. Civ. P. 37(c)(1). The lack of a reliable incremental costs analysis infects Mr. Jarosz's entire lost profits opinion, which is thus unreliable and should be excluded. *See Promega Corp. v. Life Techs. Corp*., 875 F.3d 651, 660 (Fed. Cir. 2017) ("When a patentee seeks lost profits as the measure of damages, 'the patent holder bears the burden of proving the amount of the award.'") (emphasis omitted).

V. MR. JAROSZ'S PRICE PREMIUM RESTS ON UNRELIABLE DATA

No expert would reasonably rely on estimated data he knows is off by an order of magnitude from the actual data available to him. But Mr. Jarosz does just that in the price

premium calculation he performs as part of his incremental benefits opinion and that opinion should be excluded. Ex. 10, Jarosz Op. Rep. ¶¶10, 113–115, 121–125, 191, 272, 274, Tabs 14, 16; Ex. 11, Jarosz Rpl. Rep. ¶¶106–117.

The first step in Mr. Jarosz's incremental benefits analysis "is a determination of the incremental benefits ***associated with*** the use of the patent at issue," which represents the "upper bound" for a reasonable royalty. Ex. 10, Jarosz Op. Rep. ¶114 (emphasis in original). To attempt this first step, Mr. Jarosz assumes without the support of a technical expert that Glaukos's market-leading iStent does not practice the Asserted Patents. *Id.* ¶123. He then theorizes that any purported "price premium" Hydrus "commands" over iStent is as a result of Hydrus practicing the Asserted Patents. *Id.* ¶124. That unsupported opinion should be excluded.

Furthermore, Mr. Jarosz failed to perform the analysis needed to reliably opine that Hydrus even commands a price premium over iStent (much less as a result of practicing the Asserted Patents). *See* Ex. 22, Jarosz Tr. at 178:3–10. Mr. Jarosz calculates the alleged price premium by taking Hydrus's ***actual*** Average Sales Price ("ASP") of [redacted] and subtracting from it an ***estimated*** ASP for iStent of [redacted], a misleading value he calculates based on estimates provided by third-party Market Scope for iStent procedures in Q2 2018. Ex. 10, Tab 9. Mr. Jarosz blindly accepts Market Scope's estimates, despite [redacted] Ex. 37, IVANTIS_SS_00013107 at 108. Notably, Market Scope calculates market share based on the same procedure estimates Mr. Jarosz uses to calculate his iStent ASP. Indeed, at his deposition Mr. Jarosz admitted the Market Scope procedure estimates were off by "***an order of magnitude***" compared to actual sales data. Ex. 22 at 162:8–16.

Mr. Jarosz chose not to verify the accuracy of his cherry-picked Market Scope figures,

rendering his analysis inherently and demonstrably unreliable. *See Bruno*, 311 F.R.D. at 138 ("[E]xperts who use data in their reports without independently verifying the accuracy or reliability of those figures fail to satisfy this Circuit's reliability requirement."); *Chemipal*, 350 F. Supp. 2d at 589 (excluding damages opinion when expert "did not conduct any independent analysis"); *MOSAID*, 2014 WL 807877 at *3 (expert "provided no support for the accuracy of the statements and figures" underlying opinion). Cross-examination is insufficient to remedy Mr. Jarosz's reliance on data that is off by an "order of magnitude," which would unfairly and irreparably skew the damages horizon for the jury. *ZF Meritor*, 696 F.3d at 294 ("Lack of familiarity with the methods and the reasons underlying [data] virtually precludes any assessment of the validity of the [data] through cross-examination."). The Court should exclude.

VI. DR. DOWNS'S AND MR. JAROSZ'S RESPECTIVE APPORTIONMENT ANALYSES ARE UNRELIABLE AND SHOULD BE EXCLUDED

Sight's damages expert, Mr. Jarosz, opines that the value of the patented technology is 83% of the per-unit economic value of the accused Hydrus. Ex. 10, Jarosz Op. Rep. ¶¶188–189. For that high percentage, Mr. Jarosz relies on a technological "value driver" analysis performed by Dr. Downs, in which Dr. Downs identifies differences between Hydrus and competitive devices that were advertised in Defendants' marketing, sales, and training materials. However, Dr. Downs does not purport to analyze the degree to which the alleged technological value drivers impacted sales or profits. Thus, it is unreliable for Mr. Jarosz to have adopted Dr. Downs's technological analysis as an economic apportionment.

Additionally, both Mr. Jarosz and Dr. Downs freely admit their "value driver" analysis excludes other features that gave Hydrus "lots of advantages" and "certainly contributed to [Hydrus's] success." Ex. 23, 9/22 Downs Tr. at 312:14–23; Ex. 10 ¶181; *see also* Ex. 11, Jarosz Rpl. Rep. ¶32. Yet neither Mr. Jarosz nor Dr. Downs account for those additional factors. Ex. 10

¶188. As a result, the apportionment analysis performed by Dr. Downs and used by Mr. Jarosz is unreliable and each expert's opinions based on that analysis should be excluded (Ex. 14 Downs Op. Rep. ¶¶375–385; Ex. 16, Downs Rpl. Rep. ¶¶141–149; Ex. 10, Jarosz Op. Rep. ¶¶10, 12, 113–115, 121–125, 187–189, 191, 272, 274, Tabs 9, 14, 16, 19, 20; Ex. 11 ¶¶ 102–124).

A. Background of Opinions

In his Market and Incremental Benefits reasonable royalty approaches, Mr. Jarosz purports to "apportion" the value of Hydrus that is "***attributable to*** the patent[s] at issue." Ex. 10, Jarosz Op. Rep. ¶115 (emphasis in original). But Mr. Jarosz does not calculate an apportionment factor by first identifying (or relying on a technical expert who identifies) Hydrus's patented and non-patented features and then evaluating their relative economic value. Rather, he relies on Dr. Downs, a biomedical engineer, who was not asked to independently identify the technological benefits of Hydrus and compare those to the Asserted Patents. Ex. 23, 9/22 Downs Tr. at 40:24–41:4, 304:21–305:3; Ex. 14, Downs Op. Rep. ¶384. Instead, Dr. Downs was asked to provide an overview of the benefits Defendants touted in their materials for Hydrus and identify which of those could be attributed to the Asserted Patents. Ex. 14, Downs Op. Rep. ¶375.

Out of hundreds of marketing documents produced in this case, Dr. Downs relies on eight documents[3] where Defendants allegedly identified "six purported advantages of the Hydrus Microstent, or 'value drivers,' over other MIGS devices." Ex. 14, Downs Op. Rep. ¶384. Dr. Downs then concludes that in his "technical" opinion, "five of the six purported advantages of Hydrus can be attributed to elements claimed in the claims of the Asserted Patents." *Id*. ¶385. Dr. Downs, however, did not analyze other features of Hydrus or claim that ***all*** of Hydrus' economic

[3] These documents are attached as Ex. 33, Ex. 36, Ex. 39, Ex. 40, Ex. 43, Ex. 44, Ex. 45, and Ex. 48. *See* Ex. 14, Downs Op. Rep. nn. 262, 264, 265, 268–272, 274–279. Dr. Downs provided no justification for why he limited his analysis to these eight documents.

value stems from his identified six advantages. Nor did Mr. Jarosz, who, relying exclusively on Dr. Downs's technical analysis, simply concludes that an appropriate apportionment "factor [is] five out of six (or 83 percent)." Ex. 10, Jarosz Op. Rep. ¶188.

B. Argument

An apportionment analysis is required to ensure that a reasonable royalty reflects the economic footprint of the patent and is "based on the incremental value that the patented invention adds to the end product." *Exmark Mfg Co. v. Briggs & Stratton Power Prods. Group*, 879 F.3d 1332, 1348 (Fed. Cir. 2018). Here, however, Mr. Jarosz improperly relies on Dr. Downs's flawed technical analysis as a stand-in for an economic apportionment. Both experts' opinions are unreliable and should be excluded.

1. Dr. Downs's technological apportionment should be excluded.

The only thing one can conclude from Dr. Downs's "value driver" analysis is that Defendants touted certain features of Hydrus and, according to Dr. Downs, some of those features can be attributed to the Asserted Patents. Proving the unreliability of his review, Dr. Downs admitted he did not conduct any "independent analysis" of the Asserted Patents' technological benefits, nor did he survey any physicians to determine whether any of his "value drivers" actually influence consumer demand. Ex. 23, 9/22 Downs Tr. at 304:21–305:6. Instead, he derives his "technical opinion[]" regarding Hydrus's "value drivers" from eight documents he cherry-picked that discuss the "purported benefits of the Hydrus" without explaining why those materials are a reliable proxy for a technical analysis. Ex. 14, Downs Op. Rep. ¶¶373, 375; *Cirba v. VMware*, 2023 WL 3151853 at *5 n.6 (D. Del. Apr. 18, 2023) (touting accused features "as part of marketing" fails to establish features are "the driving force for [] customer sales"); *accord Nortek Air Sols. V. Energy Lab*, 2016 WL 3856250, at *5 (N.D. Cal. July 15, 2016) (same).

Dr. Downs also does not explain his understanding of what "value driver" means, or how

his identified drivers reflect 100% of Hydrus' economic value. Nor does he explain how he selected the eight documents from which he picked his "value drivers," or why he picked only some of the mentioned "value drivers." For example, Dr. Downs cites IVANTIS_SS_00011409 (Ex. 36) at 11413 for the proposition that [redacted] Ex. 14, Downs Op. Rep. ¶376. [redacted] Ex. 40 at 11413. Without any stated justification, Dr. Downs excludes [redacted] *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Moreover, the purported value drivers identified by Dr. Downs are based on a comparison of Hydrus's marketed advantages over other commercialized products, not the extent to which patented and unpatented features affect sales and profits of Hydrus, as required for apportionment. *See supra* n.3; Ex. 22, Jarosz Tr. at 238:21–239:10; *Exmark Mfg. Co.*, 879 F.3d at 1350. Indeed, Dr. Downs is not qualified to opine on whether the purported "value drivers" impact the market value or profitability of Hydrus, or whether they cause consumers to purchase Hydrus, because Dr. Downs is an engineer, not a medical doctor or an economist. *See* Ex. 23, 9/22 Downs Tr. at 33:4–5, 40:16–21, 41:2–3, 330:19–24; Fed. R. Evid. 702 ("qualified" expert).

Furthermore, Dr. Downs concedes his enumerated "value drivers" do not account for the entirety of the Hydrus's value. For example, he admits there are "lots of advantages to nitinol," which the Hydrus is made from but which is not covered by the patents, and that those advantages make nitinol a "good biocompatible material." Ex. 23, 9/22 Downs Tr. at 312:14–23.

Dr. Downs also admits the "delivery apparatus," which is not covered by the patents, "provides certain benefits to the Hydrus." *Id.* at 313:8–11. Dr. Downs's failure to account for these additional technical advantages renders his marketing-based "value driver" analysis an unreliable proxy for an independent technical apportionment. *See Exmark*, 879 F.3d at 1350.

2. Mr. Jarosz's economic apportionment is unreliable.

Damages experts fail to properly apportion when they "acknowledge[] that other elements of the [Accused Product] affect sales and profits" but "fail[] to conduct any analysis indicating the degree to which these considerations impact the market value or profitability of the [accused product]." *Exmark*, 879 F.3d at 1350; *see also Acceleration Bay*, 2019 WL 4194060 at *5 (D. Del. Sept. 4, 2019) (excluding damages opinion where expert "admit[ted] that there are other, significant, features of the accused products that contribute economic value" but "account[ed] for none of those features" in his apportionment analysis). Here, Mr. Jarosz's repackaging of Dr. Downs's technical apportionment as an economic apportionment flunks that basic test. Dr. Downs admitted his value-driver analysis is not an effective proxy for apportionment because it excludes other features that drive Hydrus's value. Ex. 23, 9/22 Downs Tr. at 312:14–23; *id.* at 313:8–11. And just like Dr. Downs, Mr. Jarosz recognizes "other factors certainly contributed to [Hydrus's] success as well" but he makes no effort to identify or quantify them. Ex. 10, Jarosz Op. Rep. ¶181; *see also* Ex. 11, Jarosz Rpl. Rep. ¶32 ("[M]any factors can, as suggested by Mr. Meyer, influence physicians' choice among MIGS devices."). Indeed, even though Defendants' damages expert pointed out that "Ivantis's commercialization efforts and intellectual property," along with "Alcon's brand, partnerships, reimbursement amounts, customer relationships and footprint," drive sales of Hydrus, Mr. Jarosz made no attempt to carry Sight's burden to account for how those factors contribute to Hydrus's success. *See* Ex. 13, Meyer Rep. ¶182; Ex. 11, Jarosz Rpl. Rep. ¶123; *see also Omega Pats., LLC*, 13 F.45h at 1376

("[T]he patentee must in every case give evidence tending to separate or apportion[.]"); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l.*, 904 F.3d 965, 979 (Fed. Cir. 2018) (patentee must "prove that [unpatented] features do not cause consumers to purchase the product."). Both the Federal Circuit and courts in this Circuit have held that under such circumstances, an expert's apportionment opinion and the reasonable royalty opinions flowing therefrom are properly excluded. *See Exmark*, 879 F.3d at 1350; *Acceleration Bay*, 2019 WL 4194060 at *5.

Fundamentally, Mr. Jarosz's apportionment opinion fails because he does not apportion by first objectively identifying Hydrus's patented and non-patented features and then evaluating their relative economic value. Instead, he repackages Dr. Downs's "technical" summary and uses it as an economic analysis. Ex. 10 ¶188. But Mr. Jarosz does not explain if (and if so, why) the technological "value drivers" are economic value drivers. Nor does he explain what economic value should be attributed to features Dr. Downs and Mr. Jarosz credit as adding value to Hydrus, why (or if) Dr. Downs's six value drivers reflect 100% of Hydrus's value, or why each allegedly contributes equal value to Hydrus.[4] Ex. 23, 9/22 Downs Tr. at 40:24–41:4; Ex. 10 ¶188; Ex. 14 ¶373; *see Exmark*, 879 F.3d at 1350; *Acceleration Bay*, 2019 WL 4194060 at *5.

In short, Mr. Jarosz does not analyze consumer demand at all: he does not rely on any surveys that study what drives consumer purchasing or use decisions, nor does he rely on any opinions from medical doctors about why they choose Hydrus. *See Exmark*, 879 F.3d at 1350 (failing to analyze factors that "affect sales and profits" renders apportionment unreliable). Mr. Jarosz does not explain how he takes the leap from a purely "technical" opinion regarding "value

[4] Mr. Jarosz also fails to explain why Dr. Downs's "value drivers" support apportionment under *Georgia-Pacific* Factor 13. Dr. Downs provided his "value driver" analysis to support *Georgia-Pacific* Factors 9 and 10; however, Mr. Jarosz stated that those factors "provide no additional guidance here." Ex. 10, Jarosz Op. Rep. ¶178.

drivers" identified from eight marketing documents to an economic apportionment of patented versus non-patented features. *See Cirba*, 2023 WL 3151853, at *5; *Nortek Air Sols.*, 2016 WL 3856250, at *5 ("[T]he fact that a company chooses to advertise its products in a certain way says nothing about why a customer chooses to purchase a particular product."). No amount of cross-examination can unravel such an unreliable opinion, which should be kept from the jury. *See Virnetx, Inc. v. Cisco Sys.*, Inc., 767 F.3d 1308, 1328 (Fed. Cir. 2014) ("[T]he district court should have exercised its gatekeeping authority to ensure that only theories comporting with settled principles of apportionment were allowed to reach the jury.").

VII. MR. JAROSZ'S AND DR. DOWNS'S OPINIONS RELYING ON THE *GLAUKOS* SETTLEMENT AGREEMENT ARE UNRELIABLE

To calculate a reasonable royalty, Sight's damages expert relies on a 10% royalty rate from an agreement Ivantis entered into to settle patent infringement litigation with Glaukos, Ivantis's direct competitor and the market leader. However, the evidence demonstrates that Ivantis entered the agreement under extreme duress due to adverse rulings in the underlying *Glaukos* litigation, as well as [redacted] for a potential acquisition by Alcon [redacted] The use of settlement agreements in a reasonable royalty analysis is often disfavored by courts because of the coercive nature of litigation, because the royalty may have more to do with "the context of settling a litigation dispute, and thus d[oes] not reflect the royalty the parties would have reached just before infringement began." *See Zimmer Surgical, Inc. v. Stryker Corp.*, 356 F. Supp. 3d. 466, 496 (D. Del. 2019). Even more so here, where the events of the underlying *Glaukos* litigation and [redacted] of Alcon's option render Mr. Jarosz's royalty opinions based on the *Glaukos* settlement inherently unreliable. In addition, Mr. Jarosz bases technological comparability on an unreliable opinion from Sight's technical expert, Dr. Downs,

who fails to provide any meaningful comparison. Mr. Jarosz ignores all this in an effort to use the [redacted] royalty rate [redacted] *See* Ex. 21, Roeder Tr. at 108:2–18. Mr. Jarosz's and Dr. Downs's opinions regarding the *Glaukos* settlement should be excluded. *See* Ex. 10, Jarosz Op. Rep. ¶¶11, 128–131, 137–147, 163, 192, 273, Tabs 6, 14, 17, 21–22; Ex. 11, Jarosz Rpl. Rep. ¶¶88–10; Ex. 14, Downs Op. Rep. ¶¶391-408; Ex. 16, Downs Rpl. Rep. ¶156.

A. Background on the *Glaukos* Settlement and Alcon Acquisition

Ivantis was formed in 2007 with the goal of developing new and innovative solutions for glaucoma. *See* Ex. 35, IVANTIS_SS_00010599 at 599, 601. After a decade of intensive effort, in August of 2018, Ivantis received FDA approval of its Hydrus microstent for the treatment of glaucoma. *See id.* at 599. Anticipating such approval, Glaukos (the market leader in glaucoma and manufacturer of the iStent) had sued Ivantis in April 2018, accusing the Hydrus of infringing its patents. *See* Ex. 34, IVANTIS_SS_00009130 at 131.

[redacted]

Over the next three years, as the *Glaukos* case was proceeding to trial, Ivantis received a number of adverse rulings. In March of 2019, the Court granted Glaukos's motion for summary judgment that it did not infringe Ivantis's asserted patents. *See Glaukos Corp. v. Ivantis, Inc.*, 2019 WL 1950297 at *7–15 (C.D. Cal. Mar. 19, 2019). In addition, in June of 2020, the Court granted Glaukos's motion for an adverse inference based on the institution of an Ivantis email retention policy that resulted in emails being deleted during a time when the Court found Ivantis reasonably anticipated litigation with Glaukos. *See Glaukos Corp. v. Ivantis, Inc.*, 2020 WL 10501850 (C.D. Cal. June 17, 2020). [redacted]

[redacted]. *See* Ex. 46, IVANTIS_SS_00420568 at 568–571; Ex. 47, IVANTIS_SS_00445917 at 917. [redacted] *See* Ex. 46, IVANTIS_SS_00420568 at 570.

In September 2021, two weeks before trial and [redacted] Ivantis settled the *Glaukos* litigation. *See* Ex. 34, IVANTIS_SS_00009130 at 131; Ex. 27, Van Meter Tr. at 212:17-20, 238:20-239:23. The *Glaukos* settlement included two lump-sum payments of $30 million each and a 10% ongoing royalty through expiration of the Glaukos patents on April 26, 2025. *See* Ex. 30, GK00000001 at 010, 014. [redacted] limited, non-exclusive cross-license and covenant not to sue on Glaukos and Ivantis patents. *Id.* at 006–010, 014–016. Following the settlement, Alcon exercised its option in November 2021 and completed its acquisition of Ivantis in January 2022 for $475 million—[redacted]. *See* Ex. 46, IVANTIS_SS_00420568 at 570; Ex. 47, IVANTIS_SS_00445917 at 917.

B. Mr. Jarosz's Use of the *Glaukos* Agreement Is Unreliable Given Its Litigation Context

Courts have long disapproved of expert testimony that calculates damages by relying on a settlement agreement from prior litigation, as was done here. *See, e.g.*, *Rude v. Westcott*, 130 U.S. 152, 164 (1889); *ViaTech Techs. v. Adobe*, 2023 WL 5975219 at *15 (D. Del. Sept. 14,

2023); *IOENGINE, LLC v. PayPal Holdings*, 607 F. Supp. 3d 464, 505 (D. Del. 2022). The Federal Circuit has explained that the conditions of a settlement agreement "are tainted by the coercive environment of patent litigation [and] are unsuitable to prove a reasonable royalty[.]" *LaserDyanamics v. Quanta Computer*, 694 F.3d 51, 77 (Fed. Cir. 2012). Accordingly, this Court routinely excludes expert testimony that calculates a reasonable royalty by analyzing a past settlement agreement. *See e.g., ViaTech Techs.*, 2023 WL 5975219 at *15 (excluding testimony relying on settlement because of "minimal probative value"); *IOENGINE,* 607 F. Supp. 3d at 505 (excluding expert testimony relying on settlement due to lack of probative value and significant risk for prejudice); *M2M Solutions, LLC v. Enfora, Inc*., 167 F. Supp. 3d 665, 679 (D. Del. 2016) (excluding expert testimony that ignored settlement context); *AVM Techs. v. Intel*, 927 F. Supp. 2d 139, 144 (D. Del. 2013) ("[A] single settlement agreement on a different patent without any analysis of the settlement context is not a reliable method for calculating damages.").

1. The *Glaukos* settlement was heavily influenced by adverse rulings.

"[T]he propriety of using prior settlement agreements to prove the amount of a reasonable royalty is questionable," because the fact that settlement agreements "are unsuitable to prove a reasonable royalty is a logical extension of *Georgia-Pacific*." *LaserDynamics*, 694 F. 3d at 77. When an expert "fails to undertake any analysis of the underlying litigation that led to the settlement," any economic comparability conclusions "cannot be based on 'sound economic and factual predicates.'" *Art+COM Innovationpool v. Google*, 155 F. Supp. 3d 489, 511–12 (D. Del. 2016). Here, the only analysis Mr. Jarosz performs of the underlying *Glaukos* litigation is to state that "there had been no finding of the validity, enforceability, or infringement of the two patents" and to point out that the *Glaukos* settlement contained a cross-license to Ivantis patents. *See* Ex. 10 ¶¶145–147. Mr. Jarosz does not analyze the impact the spoliation finding had on the *Glaukos* settlement, [redacted]

[redacted] *See id*; Ex. 21, Roeder Tr. at 28:5-7, 108:2–109:3. Further, by not analyzing the adverse inference sanction against Ivantis, Mr. Jarosz's analysis is contrary to *LaserDynamics*, where the Federal Circuit held that a settlement agreement made under "severe legal and procedural disadvantage" due to sanctions was "the least reliable license" in the record. *See* 694 F.3d at 77–78. In fact, ***in reply***, Mr. Jarosz (who holds a JD) claimed he was unaware of "the nature" of the adverse rulings in *Glaukos* or how they could affect the royalty terms. *See* Ex. 11 ¶91; *see also* Ex. 22 at 207:5–20. Mr. Jarosz also argued (contrary to *LaserDynamics* and common sense) that "even if there were 'adverse court rulings,' that is precisely what is to be assumed in using a hypothetical negotiation construct," and speculated that assumptions about validity, enforceability, and infringement "are stronger assumptions than those presumably underlying the Glaukos-Ivantis Settlement Agreement." Ex. 11 ¶91.

Nor did Mr. Jarosz analyze the summary judgment ruling of non-infringement against Ivantis's asserted patents, which gutted Ivantis's affirmative case, or the impact that had on the royalty rate. Mr. Jarosz's failure to analyze the rulings underlying the litigation and the effect they had on the terms of the settlement agreement—including [redacted] 10% running royalty rate—requires exclusion of his opinions regarding the agreement. *See* Ex. 21, Roeder Tr. 108:2–18; *M2M Solutions*, 167 F. Supp. 3d at 675 ("It is improper to rely on license agreements that were radically different from the hypothetical agreement under consideration to determine a reasonable royalty."); *TC Technology LLC v. Sprint Corp.*, 2019 WL 2515779 at *15 (D. Del. June 18, 2019) (excluding expert opinion because the "[expert] does not even acknowledge the fact that the prior licenses are settlement agreements, let alone address how that should be considered within the context of the hypothetical negotiation.").

2. The pending Alcon acquisition substantially influenced Ivantis's decision to settle the *Glaukos* litigation.

The Alcon acquisition's [redacted] with the *Glaukos* litigation and settlement reinforces that the *Glaukos* agreement is economically non-comparable to the hypothetical negotiation. *See Zimmer*, 365 F. Supp. 3d at 496 (striking expert opinion that failed to demonstrate whether settlement agreement was "economically similar or dissimilar"); *see also* Ex. 28, Meyer Tr. at 244:9–20 (Alcon damages expert cataloging unreliable aspects of *Glaukos* settlement, [redacted] The litigation [redacted]. *See* Ex. 46, IVANTIS_SS_00420568 at 570. Unsurprisingly, [redacted] *See* Ex. 27, Van Meter Tr. at 212:10–20 [redacted] In light of [redacted], Mr. Jarosz's opinions based on the *Glaukos* agreement are unreliable. Notably, cross-examination and rebuttal evidence cannot cure any of the aforementioned issues, as that would require a trial within a trial on the spoliation ruling from the *Glaukos* litigation and the related Alcon acquisition, which is confusing, a waste of resources, and highly prejudicial. *See Daubert*, 509 U.S. at 595 (courts must be mindful of Rule 403 when exercising gatekeeping responsibilities of Rule 702); *IOENGINE*, 607 F. Supp. at 506 (considering prejudice of admitting settlement agreement under 403 when excluding expert testimony under *Daubert*).

C. Dr. Downs's Technological Assessment of the *Glaukos* Patents Is an Unreliable Basis for Mr. Jarosz's Opinions

As an economist, Mr. Jarosz is not qualified to opine on technological comparability. *See* Ex. 22, Jarosz Tr. 212:15–19. Instead, he relies on Dr. Downs to compare the asserted patents

from the *Glaukos* litigation with the asserted patents here. Ex. 10, Jarosz Op. Rep. ¶140. Dr. Downs's analysis, however, is fundamentally flawed because he compared the patents according to categories he unilaterally created: "device-specific attributes," "device kit with introducer," and "methods for reducing IOP in combination with viscoelastic fluid." Ex. 14, Downs Op. Rep. ¶398. By considering these categories across the patents, Dr. Downs concluded the Glaukos patents are narrower than Sight's asserted patents. *See id.* ¶397. Based on Dr. Downs's analysis, Mr. Jarosz opines that the royalty rates from the *Glaukos* settlement agreement are "an appropriate guidepost for a reasonable royalty." Ex. 10, Jarosz Op. Rep. ¶141.

Dr. Downs's use of undefined and imprecise categories to assess technical comparability is unreliable. *See LaserDynamics, Inc.*, 694 F.3d at 79 ("loose or vague comparability between different technologies or licenses does not suffice"); *Adasa Inc. v. Avery Dennison Corp.*, 55 F. 4th 900, 915 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 2561 (2023) (affirming comparability analysis insufficient where expert conclusions that "the licensed portfolios 'include' patents that cover 'RFID technology' says little, if anything, about their relation to the '967 patent. 'RFID technology' is too broad and vague a category, without more, to serve as a meaningful comparison point to the specific technology at issue in this case."); *Zimmer*, 365 F. Supp. 3d at 495–96 (finding failure to establish technical comparability where damages expert used "broad and nebulous language" and relied on technical expert who "generally identified the subject matter of the [] patents."). Because Dr. Downs's analysis is unreliable, his opinions flowing from that analysis and Mr. Jarosz's opinions that rely on it should be excluded.

VIII. OPINIONS OUTSIDE DR. DOWNS'S EXPERTISE SHOULD BE EXCLUDED

The Court should exclude the opinions of Dr. Downs, a biomedical engineer, who opines on the FDA approval processes (Ex. 14, Downs Op. Rep. ¶¶362–364, Ex. 16, Downs Rpl. Rep. ¶127) and the PTO's consideration of prior art references (Ex. 15, Downs Reb. Rep. ¶¶98–110)

because he is unqualified to offer such opinions. *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396 (3d Cir. 2003) ("[T]he district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury.").

Dr. Downs admits he is "not an expert on the FDA regulatory process." Ex. 23, Downs 9/22 Tr. at 41:13–19; *see also* Ex. 14 ¶¶2–8 (no experience in FDA processes). Nevertheless, he opines that in 2018, if Ivantis had modified the Hydrus design to create proposed design-arounds, it "would [] have negated 7 years' worth of clinical data Ivantis had gathered by that time, [] likely would have also required submitting a new application for approval from the FDA," "required the collection of additional clinical data," and delayed commercialization of Hydrus by "a year or more." Ex. 14 ¶364; Ex. 16 ¶127. These opinions relate to the FDA approval requirements for medical devices, ***an area in which Dr. Downs agrees he lacks expertise*** and for which he would "defer to FDA experts." Ex. 23, Downs 9/22 Tr. at 41:13–19. He should have done so here: both parties have retained actual FDA experts. Because Dr. Downs is not qualified, his opinions related to FDA approval (Ex. 14, Downs Op. Rep. ¶¶362–364, Ex. 16, Downs Rpl. Rep. ¶127) must be excluded. *In re Diet Drugs*, 2001 WL 454586 at *23–24 (E.D. Pa. Feb. 1, 2001) (microbiologist unqualified to opine on FDA regulations).

Dr. Downs also opines on whether, and to what degree, the PTO previously considered prior art references. Ex. 15, Downs Reb. Rep. ¶¶98–110; *id*. at ¶100 (opining examiner considered art that appeared on search query). Dr. Downs is not qualified to offer these opinions as he is admittedly "not an expert on patent and trademark office procedures," is not a patent lawyer, and has "never been through the patent prosecution process." Ex. 23, Downs 9/22 Tr. at 41:20–42:15. Because Dr. Downs is not qualified to opine on PTO practices and procedures, his opinions on that subject must be excluded. *See Inventio AG v. Thyssenkrupp Elevator Americas*

Corp., 2014 WL 174301 at *1 (D. Del. Jan. 14, 2014) (technical expert unqualified to testify regarding USPTO proceedings); *J&M Indus. v. Raven Indus.*, 457 F. Supp. 3d 1022 at 1047 (D. Kan. 2020) (same); *Reger v. A.I. duPont Hosp. for Children of Nemours Found.*, 259 F. App'x 499, 500 (3d Cir. 2008) ("subjective belief" "does not meet Rule 702's reliability requirement").

IX. DR. DOWNS'S NEW CLAIM CONSTRUCTIONS SHOULD BE EXCLUDED

Dr. Downs applies new claim constructions not requested by Plaintiff during claim construction and that directly contradict the Court's claim construction Order. This Court routinely excludes such opinions. *See, e.g.*, *Minerva Surgical, Inc. v. Hologic, Inc.*, 2021 WL 3048447, at *6 (D. Del. July 20, 2021) (collecting cases). Experts cannot "contradict the [district] court's construction to a jury." *Exergen v. Wal-Mart Stores*, 575 F.3d 1312, 1321 (Fed. Cir. 2009); *LP Matthews v. Bath & Body Works*, 458 F. Supp. 2d 198, 210 (D. Del. 2006).

"Does Not Significantly Block" – The Court adopted Plaintiff's proposed construction, construing these terms to mean "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." D.I. 287 at 1. The Court did so based on Plaintiff's position (at the time) that a POSA could evaluate whether these terms are met by analyzing whether a device increases total aqueous outflow from the eye or, relatedly, decreases intraocular pressure (referred to as "net efflux" of aqueous fluid). *See* Defendants' MSJ at Section III.A; D.I. 273 at 6-7; D.I. 118 at 20-21; D.I. 119, Ex. 19, 11/10/22 Downs Decl. ¶¶21, 25; D.I. 119, Ex. 20 at 141:12-142:8. The Court's construction also requires only that a device ***permit*** (i.e., not block) fluid outflow to the extent flow exists. The construction does not require that a device ***creates*** flow or that flow ***must*** occur in any particular location. Dr. Downs now ignores the Court's construction and his own claim-construction declaration, and asserts that increased outflow/decreased IOP are insufficient alone, and that "flow ***has*** to occur"

at a specific location: through the trabecular meshwork. Ex. 15, Downs Reb. Rep. ¶¶147-49, 167-79; Ex. 23, 9/22 Downs Tr. at 85:15-86:8, 208:12-211:13; *see* Ex. 15, Downs Reb. Rep. ¶¶146-192, 247-279, 375-412, 464-491, 538, 542-576. His new opinions requiring that aqueous humor ***must*** flow at any specific location should be excluded.

"Arcuate Member" – The Court construed this term to mean "a structure having one or more curved portions," rejecting Plaintiff's proposed construction of "a structure that is arced or bowed [along the length of the structure]." D.I. 287 at 1; D.I. 134 at 16. Dr. Downs now injects three different, additional limitations. ***First***, he interprets "a structure having one or more curved portions" to mean a structure that is curved along its entire length (Ex. 24, 9/28 Downs Tr. at 164:19-165:22, 255:2-256:10), i.e., Dr. Downs rejects the Court's construction and reverts to Plaintiff's proposal. ***Second***, Dr. Downs contends "a curved portion" means "a curved portion of a certain size." For example, Dr. Downs contends a device disclosed by prior-art reference Gharib, which he admits discloses a curved "joint," is not "curved" because the "joint's" radius of curvature is not large enough. Ex. 15, Downs Reb. Rep. ¶¶142-43; Ex. 24, 9/28 Downs Tr. at 166:11-12, 257:4-260:13, 261:7-262:11, 264:20-277:17. But Dr. Downs could not give any guidance on the size at which a curved joint is a "curved portion" under the construction. *Id*. This reads an ambiguous and undefined size limitation into "curved portion" that is not in the Court's construction. ***Third***, Dr. Downs admits he is requiring the curved portion to be "preformed," which is absent from the Court's construction, to argue that certain prior art references do not meet this limitation despite that they are curved when implanted. Ex. 24, 9/28 Downs Tr. 264:16-19; *see also* Ex 15, Downs Reb. Rep. ¶¶344-47. These additional limitations Dr. Downs reads into the Court's construction should be excluded. *See Exergen*, 575 F.3d at 1321; *see* Ex. 15, Downs Reb. Rep. ¶¶131, 134-143, 345-353, 359-62, 367, 370-72, 450-453, 459, 537.

"Maintain the Patency" – The Court did not construe this term (it was not requested), and Plaintiff did not even dispute Defendants' contention that the prior art meets it. Ex. 65, Plaintiff's Resp. to Interrog. No. 8. Despite Plaintiff conceding the prior art meets this term, Dr. Downs proposes a new construction that he relies on to argue the prior art does not meet this term. *See* Ex. 15, Downs Reb. Rep. ¶¶126-29, 228-231, 339-342, 444-47, 523-26, 662-65, 699-702, 740-43, 768-69, 799-801, 870-72, 1088, 1114. Moreover, Dr. Downs concedes that, consistent with the prior art, the plain meaning of "maintain the patency" is "to hold a structure open." Ex. 24, 9/28 Downs Tr. at 208:6-209:24; Ex. 31, Lynch-197 at 8:22-23. Yet Dr. Downs uses a non-plain-meaning construction based on his interpretation of the specification, and also reads into his construction additional, allegedly "inherent," limitations, Ex. 23, 9/22 Downs Tr. at 64:24-75:18, which are likely to confuse and mislead a jury. *Sprint Commc'ns Co. v. Cox Commc'ns*, 302 F. Supp. 3d 597, 620 (D. Del. 2017). Plaintiff's late attempt to shoehorn in a non-plain-meaning construction is waived and should be excluded. *CytoLogix v. Ventana Med. Sys.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005) ("The risk of confusing the jury is high when experts opine on claim construction before the jury."); *CAO Lighting v. Gen. Elec. Co.*, 2023 WL 1930354, at *6 (D. Del. Jan. 30, 2023) (excluding new construction); *Trackthings v. Netgear*, 2023 WL 5993186, at *2 (D. Del. Sept. 15, 2023). The plain meaning ("to hold a structure open") should apply. Ex. 31, Lynch-197 at 8:22-23; Ex. 24, 9/28 Downs Tr. at 208:6-209:24.

"Implantable Circumferentially within Schlemm's Canal" – The Court did not construe this term (it was not requested), and Plaintiff did not dispute that the prior art meets it. Ex. 65, Plaintiff's Resp. to Interrog. No. 8. Despite Plaintiff's concession, and despite Dr. Downs's own plain-meaning construction in his Opening Report, Dr. Downs applies a new and contradictory construction in his Rebuttal Report to avoid prior art. *Compare* Ex. 14, Downs Op.

Rep. ¶200 ("A POSA would understand" this term "means longitudinal or lengthwise insertion around the circumference of Schlemm's canal, as indicated by the patent.") *with* Ex. 15, Downs Reb. Rep. ¶¶123-25 (This term means "inserted into Schlemm's canal in a single direction, i.e. is inserted into Schlemm's canal in a unidirectional manner with respect to the point of insertion."). His later construction also contradicts the specification, Ex. 18, Tanna Rpl. Rep. ¶88; Ex. 14, Downs Op. Rep. ¶200 (citing Ex. 2, '443 Patent at 8:54-56), and should be excluded.

"Fenestration" – Neither party asked the Court to construe "fenestration," and Plaintiff proposed during claim construction that the plain and ordinary meaning of "fenestration" is "a window or opening." D.I. 90 at 2-3. Named inventor David Badawi agrees with this construction, Ex. 25, D. Badawi Tr. at 133:15-18, as did Dr. Downs in his Opening Infringement Report. Ex. 14, Downs Op. Rep. ¶72; *see also* Ex. 24, 9/28 Downs Tr. 247:8-18. But Dr. Downs then changed course by creating and relying on a different construction in his Rebuttal Invalidity Report ("a closed-boundary window or opening") to avoid prior art. Ex. 15, Downs Reb. Rep. ¶¶159, 194, 493. Dr. Downs's corresponding testimony should be excluded.

X. DR. DOWNS'S STRAIN ANALYSIS SHOULD BE EXCLUDED

Dr. Downs's alleged "strain analysis" should be excluded because it: (1) is improperly based on proportions in a patent figure, and (2) applies an unsupported and unreliable equation. ***First***, Dr. Downs concedes his analysis is based on "assuming that the…[patent figure] provides the proportions of this device." Ex. 24, 9/28 Downs Tr. at 170:8-23; Ex. 15, Downs Reb. Rep. ¶¶205-215. Such assumptions are legally improper, as Dr. Downs himself understands (Ex. 15, Downs Reb. Rep. ¶111), rendering his opinions unreliable and inadmissible. *Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005); *Hockerson–Halberstadt v. Avia Grp. Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000). ***Second***, Dr. Downs fails to cite any support for the equation he uses for the alleged "maximum strain," its reliability, or its application to proportions in a two-

dimensional figure of a three-dimensional device. *Heller v. Shaw Indus.*, 167 F.3d 146, 163-65 (3d Cir. 1999). Indeed, baked into Dr. Downs's analysis is the assumption that strain can be calculated based on a device's thickness, without regard to its height, width, or the cross-sectional area that bears the alleged strain. These assumptions are unsupported, do not meet the *Daubert* standard for reliability, and should be excluded. *Id.*; *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, 2016 WL 3854534, at *13 (E.D. Pa. July 14, 2016).

XI. CONCLUSION

Alcon respectfully requests that the Court exclude the opinions identified above.

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